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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------------|------------------|
| 10/685,837 | 10/15/2003 | Jost Seibler | 100725-38 / Kreisler 1109 | 8812 |
| 27384 | 7590 | 09/23/2005 | EXAMINER | |
| NORRIS, MC LAUGHLIN & MARCUS, PA 875 THIRD STREET 18TH FLOOR NEW YORK, NY 10022 | | | SINGH, ANOOP KUMAR | |
| | | ART UNIT | | PAPER NUMBER |
| | | | | 1632 |

DATE MAILED: 09/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-------------------------|------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/685,837 | SEIBLER ET AL. |
| | Examiner Anoop Singh | Art Unit 1632 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-30 is/are pending in the application.
 - 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
 - 5) Claim(s) ____ is/are allowed.
 - 6) Claim(s) ____ is/are rejected.
 - 7) Claim(s) ____ is/are objected to.
 - 8) Claim(s) 1-30 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. Claims 1-30 are pending.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-26 and 30, drawn to a method for constitutive and/or inducible gene knock down in a vertebrate, classified in class 800, subclass 21.
 - II. Claims 1-25 and 30, drawn to a method for constitutive and/or inducible gene knock down in a tissue culture, classified in class 435, subclass 325.
 - III. Claims 1-25 and 30, drawn to a method for constitutive and/or inducible gene knock down in a cell culture, classified in class 435, subclass 455.
 - IV. Claims 27, drawn to a vertebrate having stable integration at Polymerase II dependent locus, an expression vector comprising an shRNA construct, classified in class 800, subclass 21.
 - V. Claims 27-29, drawn to a tissue derived from a vertebrate having stable integration of an expression vector comprising an shRNA construct, classified in class 435, subclass 325.
 - VI. Claims 27-29, drawn to a cell culture derived from a vertebrate having stable integration of an expression vector comprising an shRNA construct, classified in class 435, subclass 455.
3. The inventions of groups I-III patentably distinct, each from other because they are drawn to methods that have distinct steps and use material compositions that have distinct structure, function and utility. For example, the method of group I require vertebrate, while the method of groups II and III require tissue and recombinant cell respectively. Additionally utilities of tissues or cells are distinct and different from those of a vertebrate, which are directed to a different class and subclass, and are structurally and functionally different from inventions of groups II and III.

The Inventions of groups IV-VI are patentably distinct because they are drawn to compositions that have distinct structure, function, and mode of utilities. For example, the invention of group IV is drawn to a vertebrate, while invention of group V and VI requires tissue and cell respectively. They have distinct physical structure and function. Additionally, vertebrate can be used for screening drugs or disease treatment model. In contrast, cells can be used for gene expression or in vitro analysis while tissue can be used for ex vivo analysis. Searches for compositions used in groups IV, V and VI will not be coextensive in the patent and non-patent literature; for example, searching for vertebrate or tissue will not be coextensive with cell culture.

The compositions of groups IV-VI are patentably distinct each from the method of groups I-III because the compositions may not be used in methods or will be used in more than one method.

Therefore, the inventions of group I-VI are patentably distinct from each other and will require separate and non-coextensive searches in the patent and non-patent literature.

Election of Species

Claim 5 generic to a plurality of disclosed patentably distinct species comprising Rosa26, collagen, RNA polymerase, actin and HPRT locus.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claim 6 generic to a plurality of disclosed patentably distinct species comprising splice acceptor sequences, polyadenylation sites, selectable markers etc.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed

Claims 7 generic to a plurality of disclosed patentably distinct species comprising group of Polymerase I, II and III dependent promoter.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claim 9 generic to a plurality of disclosed patentably distinct species comprising group of ubiquitous promoter comprising from a group consisting of a CMV promoter, a CAGGS promoter, a snRNA promoter such as U6, a RNase P RNA promoter such as H1, a tRNA promoter, a 7SL RNA promoter, a 5SrRNA promoter and other listed promoter.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claim 12 generic to a plurality of disclosed patentably distinct species comprising group of inducible promoter comprising from a group consisting of tet, Gal4, lac and any other listed promoter.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be

traversed (37 CFR 1.143). Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anoop Singh whose telephone number is (571) 272-3306. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272- 0735. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Anoop Singh
Examiner, AU 1632



RAM R. SHUKLA, PH.D.
SUPERVISORY PATENT EXAMINER